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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,732	09/18/2001	Ralf M. Luche	200125.433	9468

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
SAIDHA, TEKCHAND	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/955,732	LUCHE ET AL.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11.25.2003 (election)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-98* is/are pending in the application.

4a) Of the above claim(s) *1 and 15-98* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election

1. Applicant's election of Group V, claims 2-14, filed November 25, 2003, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. **Claims withdrawn** :

Claims 1 and 15-98 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been treated as not traversed as explained above.

3. ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

4. The examiner for this application has changed. Please make a note of it.

5. ***35 U.S.C. § 112, first paragraph (Written Description)***

Claims 2-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims recite 'an isolated polynucleotide that encodes at least 10 or 15 consecutive amino acids of a polypeptide of SEQ ID NO: 2' and vector or host cell

comprising the short polynucleotide sequence (claims 2-5); or where the isolated polynucleotide encodes a polypeptide having the sequence of DSP-15 of SEQ ID NO : 2 or a variant thereof that is modified one or more deletion, addition, insertion or substitution resulting in a sequence change of no more 50% (claim 6); or a modified polynucleotide of claim 6 that comprises SEQ ID NO : 1 (claim 7); or vectors or host cells comprising the modified SEQ ID NO : 1 and method of making DSP-15 polypeptide (claims 8-9 & 14); an antisense polynucleotide comprising at least 15 consecutive nucleotides (claim 10); or a polynucleotide that hybridizes to the compliment of SEQ ID NO : 1 under specific wash conditions (claim 11) and vector or host cell comprising such a compliment (claims 12-13).

The specification, however, only provides one representative species from *Homo sapien* of SEQ ID NO : 1 (1980 nucleotides in length) encoding a dual specificity phosphatase (DSP-15) of SEQ ID NO : 2 (659 amino acids in length) that is capable of dephosphorylating both phosphotyrosine and phosphothreonine/serine (see sequence listing and instant specification, page 2, lines 3-5).

There is no disclosure of any particular structure to function/activity relationship in the single disclosed species to the claimed modified sequences or sequences of varying lengths (for example, polynucleotide encoding 10 or 15 amino acids; or antisense polynucleotide comprising 15 consecutive nucleotide); or to other species where such sequences are conserved in order to establish a relationship among species or modify the enzyme by substitution, deletion or addition in order to make a polypeptide at least 50% identical to SEQ ID NO : 2 and still have DSP-15 activity. The

specification also fails to describe additional representative species of the DSP-15 by any identifying functional characteristics other than the fragment size or modifications of specific sequences recited in claims, for which no predictability of function is apparent. No description is given regarding the stringency (low, medium or high) of hybridization as well as the specific hybridization conditions required, apart from the conditions including the wash protocol. Given the lack of additional representative species, such as that discussed above, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Therefore, the written description requirement is not satisfied.

Enablement

6. Claims 2-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding dual specificity phosphatase of SEQ ID NO: 2, does not reasonably provide enablement for any polynucleotide fragment (30 or 45 nucleotides in length) encoding a polypeptide 10 or 15 amino acid in length or vector/host cell comprising such a polynucleotide (claims 2-5); or a polynucleotide encoding a DSP-15 polypeptide having 50% identity to SEQ ID NO: 2 or vector/host cell comprising such a polynucleotide (claims 6-9). The specification also does not provide enablement an antisense polynucleotide comprising at least 15 consecutive nucleotides or a polynucleotide that detectably hybridizes to a compliment of the sequence of SEQ ID NO : 1 under stringency conditions not defined in the specifications. The specification does not enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of variant/fragments of the polynucleotides of SEQ ID NO : 1 broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of DSP 15 polypeptide of SEQ ID NO : 2.

No guidance is provided regarding how to make the make polynucleotide fragments of 30 or 45 nucleotides in length that would encode a functional and bioactive polypeptide 10 or 15 amino acids in length. Further no guidance or examples are provided for making a variant polynucleotide encoding a variant DSP-15 wherein the polypeptide is modified to the extent of 50%. While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications of polynucleotide(s) encoding DSP-15 polypeptide(s) for use in construction of vector, host cell or in the method of making the protein recombinantly, as encompassed by the instant claims, and the positions within a protein's sequence where

amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable, specially in view of the dual specificity of the phosphatase (DSP-15) of SEQ ID NO : 2, i.e., dephosphorylating both phosphotyrosine and phosphothreonine/serine. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications of any polynucleotide encoding DSP-15 polypeptide with 50% identity to the DSP-15 polypeptide of SEQ ID NOS: 2, because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting DSP-15 activity; (B) the general tolerance of DSP-15 polypetides to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any DSP-15 residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

With regard to claims 11-14, directed to a polynucleotide sequence that hybridizes to the disclosed sequences, Applicants have not sufficiently defined the conditions under which the hybridizations are to take place. Nucleic acid hybridization assays are extremely sensitive to the conditions in which they are performed. The buffer composition, pH, temperature, length of time, salt concentrations, quality and source of template nucleic acid, are all variables which determine the reproducibility of a

given hybridization experiment. Given the unpredictability of the art and the nature of hybridization experiments in general, it is not sufficient to merely cite hybridization wash conditions without a clear and explicit recitation of the conditions associated with the hybridization. For example, the definition of stringency as it pertains to hybridization conditions is subject to interpretation and is different from laboratory to laboratory. Therefore, without a clear and explicit recitation of the conditions which were actually used by Applicants in isolating the claimed polynucleotides which hybridize to the disclosed sequences, the skilled artisan would not be able to practice the claimed invention and would not be reasonably apprised of the metes and bounds of the claimed invention. Without such guidance, the experimentation left to those skilled in the art is undue. Including in the claims the exact nature of the hybridization conditions used to isolate the claimed polynucleotides would aid in overcoming this portion of the rejection.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including polynucleotide(s) encoding DSP-15 with an enormous number of amino acid modifications of the of SEQ ID NOS: 2. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polynucleotide(s) encoding DSP-15 having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue in using the modified enzyme in the method claimed. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

7. ***35 U.S.C. § 112, second paragraph***

Claims 6-9 & 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 & 14 recite not so common abbreviations, viz., 'DSP-15 and/or MAP....'. The claims are indefinite for such a recitation. The first use of not so common abbreviation(s) must be spelled out, which may be abbreviated in the subsequent claims.

8 Applicants provisional application 60/233,833, filed 09.19.2000, is acknowledged and this date will be considered for prior art purposes.

9. ***Claim Rejections - 35 USC § 102***

A person shall be entitled to a patent unless -

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2-3 & 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Liou et al. [WO 02/20732 A2, **7 September 2000**]. Liou et al. teach a polynucleotide (accession no. ABL40801) encoding human MAP-kinase phosphatase like-enzyme [see the enclosed sequence alignment between Applicants' SEQ ID NO : 1 and accession no. ABL40801]. There are two regions of about 323 & 480 contiguous nucleotide matches between the two sequences and an overall sequence identity of about 35%.

Such a sequence will inherently encode at least 10 or 15 consecutive amino acids and therefore anticipates the claimed invention.

10. Claims 2-3 & 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al. [WO 02/22660 A2, **11 September 2000**]. Tang et al. teach a polynucleotide sequence [Accession No. ABN59832, see the enclosed sequence search alignment] that aligns and has a 100% match with Applicants' first 851 nucleotides of SEQ ID NO : 1, and has an overall sequence identity of 43%. Such a sequence will inherently encode at least 10 or 15 consecutive amino acids and therefore anticipates the claimed invention.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. □ 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 2-3 and 10 are rejected under 35 U.S.C. 102(a) as being anticipated by EST Accession No. BE531347 for similar reasons as explained in items 9 and 10 [see the enclosed sequence search alignment showing about 710 consecutive nucleotide matches between the two sequences and an over all sequence homology of about 36%].

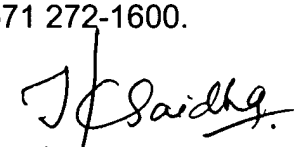
12 No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha (Ph.D.) whose telephone number is

(571) 272-0940. The examiner can normally be reached on Monday-Friday from 8:15 am to 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number is (571) 273-0940.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 571 272-1600.



Tekchand Saidha
Primary Examiner, Art Unit 1652
Recombinant Enzymes
E03A61 Remsen Bld. (Office), 400 Dulany Street
Alexandria, VA